UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
CENTRAL ISLIP COURTHOUSE

Erin Neu, individually and on behalf of all others similarly situated, Plaintiff, - against - Rite Aid Corporation, Defendant	2:23-cv-03242 Class Action Complaint Jury Trial Demanded

Plaintiff alleges upon information and belief, except for allegations about Plaintiff, which are based on personal knowledge:

1. Rite Aid Corporation ("Defendant") manufactures adhesive patches promising to deliver 4% lidocaine under the Rite Aid brand ("Product").

2. The front label representations include "Maximum Strength," "Pain Relief Lidocaine Patch," "Topical Anesthetic," "Lasts up to 12 hours," "4% Lidocaine," "desensitizes aggravated

nerves & relieves pain," "Medicated for targeted pain relief," "Stay-put flexible path," "No-mess, easy to apply and remove," "Compare to the active ingredient of Salonpas Maximum Strength Lidocaine Patch*" and "Odor free," with radiating circles on the package alluding to the Product's ability to decrease and/or eliminate pain.

I. LIDOCAINE BACKGROUND

3. Lidocaine is a topical anesthetic used to treat pain by blocking the transmission of pain signals from nerve endings in the skin to the spinal cord and brain.

4. Doctors discovered that lidocaine patches are effective in treating general neuropathic pain like muscle and spinal aches and began prescribing the patches off-label.

5. A 2012 study found that over 82% of the usage of prescription lidocaine patches were off-label.

6. As the use of lidocaine patches increased, national brands such as Salonpas and Aspercreme spend significant amounts of money to advertise their over-the-counter ("OTC") patches as equivalent to those available only with a prescription.

7. In 1983, the Food and Drug Administration ("FDA") issued requirements for the labeling, ingredients, uses, and doses of external analgesic products, allowing the use of lidocaine at 4% in the form of an ointment.

8. The first lidocaine patch was approved in 1999 to help reduce pain associated with post-herpetic neuralgia ("PHN"), a complication of shingles.

9. In 2003, the FDA began review of OTC patches to determine the safe and effective concentration of lidocaine in this format.

10. In 2013, the FDA concluded that lidocaine patches were not "generally recognized as safe and effective" for OTC use because there was insufficient information about how often the

plaster or poultice needed to be changed.

II. PRODUCT FAILS TO DELIVER LIDOCAINE IN PROMISED WAY DUE TO ADHESION DEFECTS

A. How Lidocaine Patches Work

11. Lidocaine patches use transdermal/topical delivery systems ("TDS"), which have three main parts: (1) an outer protective backing membrane, (2) a drug-in-adhesive layer, and (3) a release liner that controls the rate and extent of drug administration.

12. This is a different method of delivering medication, and the strength cannot be determined based on the FDA regulations.

13. Manufacturers of lidocaine patches attempt to get their patches to meet the FDA's 4% benchmark based on the mass of drug relative to the mass of the adhesive per patch.

14. However, the amount of lidocaine contained in, or delivered by, a lidocaine patch cannot be determined based on the arbitrary measure of a patch's drug-to-adhesive ratio.

15. This allows Defendant to alter the total mass of lidocaine contained in the Product by adjusting the thickness of the patches' back membrane without changing its dimensions.

16. This drug-to-adhesive ratio is misleading to consumers and doctors alike, who ordinarily expect that the percentage of an active ingredient in a drug has a direct correlation to the quantity, or efficacy, of that ingredient within the drug.

B. Adhesion Failure Defects

17. Since adequate adhesion is critical for such delivery systems, if a patch lifts or detaches while walking, sleeping or exercising, dosing will be compromised.

18. The FDA Adverse Events Reporting System ("AERS") revealed that approximately 70% of consumer complaints about such products, including upon information and belief, Defendant's Product, relate to their poor adhesion.

19. The FDA concluded that such patches systemically fail to adhere to the body and cannot provide the claimed pain relief.

20. This is in line with complaints made by purchasers of the Product to Defendant about its lack of adhesion abilities.

21. A peer-reviewed study published in January of 2021 by the Journal of Pain Research found that none of the generic prescription lidocaine patches it analyzed exceeded ninety percent adhesion within the twelve hour testing period.

22. Rather, their average adhesion after twelve hours was less than forty percent.

23. This was based on a scale where zero percent reflects complete detachment and fifty percent reflects half the patch lifting off the skin but not detached.

24. This is especially notable because the study required participants were sedentary while the patches were applied, whereas typical users are active and trying to function as they otherwise would, i.e., walking, exercising, etc.

25. Although the study tested generic lidocaine patches, upon information and belief, the Product, upon information and belief, the Product uses the same defective adhesion technology and has not undergone the rigorous approval process by the FDA.

26. Though other companies have innovated their technology based on clinical studies to ensure that their lidocaine patches are sufficiently flexible to adhere to a consumer's body during exercise and other everyday activity, upon information and belief, Defendant has not.

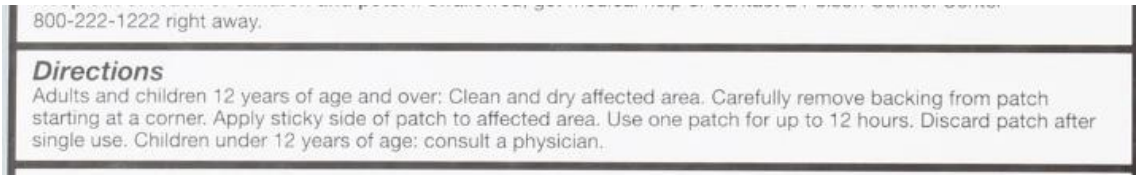
27. This is crucial because "[a]dequate adhesion is a critical quality attribute for topical delivery systems; if the product lifts or detaches during wear, dosing may be compromised and there is an increased risk of inadvertent exposure to others."

28. Since the Product cannot adhere to a person's skin throughout the promised time

period, it cannot deliver the active anesthetic ingredient of lidocaine during that time.

29. When consumers see the promise that the pain relief will "Last[s] Up To 12 Hours" by "desensitize[ing] aggravated nerves & reliev[ing] pain" because the Product is "medicated for targeted pain relief" in a "Stay-put flexible patch," they will expect it will adhere to their bodies for no less than twelve hours.

30. The Directions on the back panel Drug Facts confirm the Product will adhere for twelve hours because it tells users to "Use one patch for up to 12 hour" and then "Discard patch after single use."


800-222-1222 right away.

Directions
Adults and children 12 years of age and over: Clean and dry affected area. Carefully remove backing from patch starting at a corner. Apply sticky side of patch to affected area. Use one patch for up to 12 hours. Discard patch after single use. Children under 12 years of age: consult a physician.

31. However, the Product cannot adhere for any time even approaching twelve hours, which renders the Directions misleading, because it assumes it will not have detached by then.

32. Studies have shown the Product is unable to adhere to the skin for more than four hours, often peeling off within minutes of light activity, which renders the "Up to 12 Hours of Relief" misleading, because this is a significant disparity between what is promised and what is delivered.

III. MAXIMUM STRENGTH CLAIM IS MISLEADING

33. The representation of "Maximum Strength" is misleading for multiple reasons.

34. First, there are superior prescription lidocaine patches on the market that deliver a higher amount of lidocaine, including 5% and 1.8% prescription-strength lidocaine patches.

35. Adhesive technology exists which delivers the bioequivalence of 5% lidocaine in

patch form and maintain adhesion for at least twelve hours under normal conditions.[1]

36. Second, the FDA cautioned manufacturers of OTC analgesic products against making "maximum strength" claims because higher strength and greater potency versions of such items were available with a prescription.

37. Third, the FDA knew other more concentrated and potent similar products could appear in proximity to those represented as "maximum strength" on store shelves.

38. The result would be that consumers would be misled when other companies labeled their products as "regular strength," even though both had the same amount of medication and/or active ingredients.

39. Fourth, given that the Product is explicitly compared to Salonpas on its front label, "maximum strength" is misleading because the Rite Aid product contains roughly forty percent less lidocaine, even though they have similar or identical dimensions.

40. Fifth, numerous studies and reports revealed that users of adhesive lidocaine patches using the same technology used by the Product regularly peel off a user's skin within three to four hours, and sometimes minutes, after being applied.

41. Since, according to the FDA, the actual strength of a lidocaine patch is measured by the "mass of drug relative to the mass of the adhesive per patch" delivered to the target area, these adhesion deficiencies cause the delivery and absorption of lidocaine to be greatly reduced.

42. This inability to adhere for anywhere close to twelve hours means the Product cannot deliver the "Maximum Strength" amount of lidocaine.

IV. DESENSITIZING CLAIMS

[1] In studies, this technology maintained a mean adhesion >90% across all time points (0, 3, 6, 9, and 12 h).

43. The Product's promise to "Desensitize[s] Aggravated Nerves" is misleading because it implies its use will completely block and numb nerves and pain receptors, eliminate responses to painful stimuli, and treat neuropathic and musculoskeletal pain, including back and spinal pain.

44. The FDA determined that statements about desensitizing nerves and numbing pain were misleading in the context of these transdermal patch delivery systems.

45. This is because consumers, including Plaintiff, associate such statements with medical treatments requiring a prescription and FDA approval.

46. However, the Product is available without a prescription and has not been approved by the FDA.

47. The front label promise to "Desensitize[s] Aggravated Nerves" is inconsistent and contradictory with its limited approval to "[f]or temporary relief of pain," indicated only in the fine print of the Drug Facts on the back label.

V. DEFENDANT'S AWARENESS OF MISLEADING MARKETING OF ITS LIDOCAINE PATCHES

Jurisdiction and Venue

48. Jurisdiction is based on the Class Action Fairness Act of 2005 ("CAFA"). 28 U.S.C. § 1332(d)(2).

49. The aggregate amount in controversy exceeds $5 million, including any statutory and punitive damages, exclusive of interest and costs.

50. Plaintiff is a citizen of New York.

51. Defendant is a Delaware corporation with a principal place of business in Minnesota.

52. The members of the class Plaintiff seeks to represent are more than 100, because the

Product has been sold with the representations described here for several years, from Defendant's hundreds of stores within this State, and thousands in the States covered by Plaintiff's proposed classes, and from its website.

53. Venue is in this District with assignment to the Central Islip Courthouse because a substantial part of the events or omissions giving rise to these claims occurred in Suffolk County, including Plaintiff's purchase and/or use of the Product and awareness and/or experiences of and with the issues described here and Plaintiff resides in this District.

Parties

54. Plaintiff Jesse Sheiner is a citizen of Pittston, New York, Suffolk County.

55. Defendant Rite Aid Corporation, is a Delaware corporation with a principal place of business in Camp Hill, Pennsylvania, Cumberland County.

56.

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59. Defendant is one of the largest and most trusted retailers in the country for prescriptions, OTC items, food, household goods and other sundries.

60. Defendant even offers medical services such as necessary vaccines to customers, often at no charge.

61. Since people trust Defendant to dispense medication prescribed by their doctors, they carry that trust over to other products which satisfy other essential needs, like OTC products.

62. While Defendant sells leading national brands, they also sold a large number of OTC products under their private label Rite Aid brand.

63. Private label products are made by third-party manufacturers and sold under the

name of the retailer, or its sub-brands.

64. Previously referred to as "generic" or "store brand," private label products have increased in quality, and often are superior to their national brand counterparts.

65. Products under the Rite Aid brand have an industry-wide reputation for quality and value.

66. In releasing products under the Rite Aid brand, Defendant's foremost criteria was high-quality equal to or better than the national brands.

67. Defendant was and is able to get national brands to produce its private label items due its loyal customer base, history of high quality items and tough negotiating.

68. That Rite Aid branded products met this high bar was proven by focus groups, which rated them above the name brand equivalents.

69. Private label products generate higher profits because national brands spend significantly more on marketing, contributing to their higher prices.

70. A survey by The Nielsen Co. "found nearly three out of four American consumers believe store brands are good alternatives to national brands, and more than 60 percent consider them to be just as good."

71. Private label products under the Rite Aid brand benefit by their association with consumers' appreciation and trust for Rite Aid, as an important part of the communities it operates in.

72. The development of private label items is a growth area for Rite Aid, as it selects only top suppliers to develop and produce Rite Aid products.

73. The Rite Aid product was introduced following the release of national brands of lidocaine patches, capitalizing on their popularity and efficacy.

74. Defendant knew purchasers like Plaintiff would see "maximum strength" and think the Product was comparable to prescription-strength lidocaine products, because consumers were aware of the industry-leading Salonpas brand which has made those comparisons for its products for several years.

75. Defendant knew the "maximum strength" claim would mislead such purchasers because it was aware of their adhesion failures through communications from customers via its website, social media and direct mail, among other means.

76. Defendant did not tell Plaintiff and consumers the Product was prone to greater detachment when engaged in regular daily activities such as walking and sleeping.

77. As a result of the false and misleading representations, the Product is sold at a premium price, approximately no less than no less than $8.99 per box of six patches, excluding tax and sales, higher than similar products, represented in a non-misleading way, and higher than it would be sold for absent the misleading representations and omissions.

78. Plaintiff purchased the Product at Defendant's retail stores in New York such as in Suffolk County, between May 2021 and April 2023, and/or among other times.

79. Plaintiff purchased the Product to provide pain relief to her neck, back, elbows and shoulders.

80. Plaintiff saw the Product was labeled and marketed as "Maximum Strength" and capable of delivering 4% lidocaine which would "Last[s] Up to 12 Hours," and would "desensitize aggravated nerves" by providing "targeted pain relief" to the areas it was applied.

81. Plaintiff believed and expected the Product would reliably adhere to her body to deliver 4% lidocaine for not less than twelve hours, that they were the maximum strength available, would relieve pain, deliver pain relief through desensitizing aggravated nerves, because that is

what the representations and omissions said and implied.

82. Plaintiff expected the Product's use would completely block and numb nerves and pain receptors, eliminate responses to painful stimuli, and treat neuropathic and musculoskeletal pain, including back and spinal pain.

83. Plaintiff relied on the words, terms coloring, descriptions, layout, placement, packaging, hang tags, and/or images on the Product, on the labeling, statements, omissions, claims, statements, and instructions, made by Defendant or at its directions, in digital, print and/or social media, which accompanied the Product and separately, through in-store, digital, audio, and print marketing.

84. However, the Product did not reliably adhere to Plaintiff's body for anywhere close to twelve hours, which prevented it from providing even temporary pain relief.

85. Plaintiff bought the Product at or exceeding the above-referenced price.

86. Plaintiff paid more for the Product than she would have had she known the representations and omissions were false and misleading, or would not have purchased it.

87. The value of the Product that Plaintiff purchased was materially less than its value as represented by Defendant.

88. Plaintiff chose between Defendant's Product and similarly represented yet truthful products which did not misrepresent their attributes, features, and/or components.

Class Allegations

89. Plaintiff seeks certification under Fed. R. Civ. P. 23 of the following classes:

> **New York Class:** All persons in the State of New York who purchased the Product during the statutes of limitations for each cause of action alleged; and
>
> **Consumer Fraud Multi-State Class**: All persons in the States of West Virginia, Montana, Wyoming, Idaho, Alaska, Kansas, Nebraska, North Dakota,

Iowa, Mississippi, Arkansas, and Utah who purchased the Product during the statutes of limitations for each cause of action alleged.

90. Common questions of issues, law, and fact predominate and include whether Defendant's representations were and are misleading and if Plaintiff and class members are entitled to damages.

91. Plaintiff's claims and basis for relief are typical to other members because all were subjected to the same unfair, misleading, and deceptive representations, omissions, and actions.

92. Plaintiff is an adequate representative because her interests do not conflict with other members.

93. No individual inquiry is necessary since the focus is only on Defendant's practices and the class is definable and ascertainable.

94. Individual actions would risk inconsistent results, be repetitive and are impractical to justify, as the claims are modest relative to the scope of the harm.

95. Plaintiff's counsel is competent and experienced in complex class action litigation and intends to protect class members' interests adequately and fairly.

New York General Business Law ("GBL") §§ 349 and 350
(New York Class)

96. Plaintiff incorporates by reference all preceding paragraphs.

97. Plaintiff believed the Product would reliably adhere to her body and provide a continuous dose of maximum strength lidocaine to desensitize nerves and numb pain.

98. Defendant's false, misleading and deceptive representations and omissions are material in that they are likely to influence consumer purchasing decisions.

99. Plaintiff would not have purchased the Product or paid as much if the true facts had been known, suffering damages.

Violation of State Consumer Fraud Acts
(Consumer Fraud Multi-State Class)

100. The Consumer Fraud Acts of the States in the Consumer Fraud Multi-State Class are similar to the consumer protection statute invoked by Plaintiff and prohibit the use of unfair or deceptive business practices in the conduct of commerce.

101. The members of the Consumer Fraud Multi-State Class reserve their rights to assert their consumer protection claims under the Consumer Fraud Acts of the States they represent and/or the consumer protection statute invoked by Plaintiff.

102. Defendant intended that members of the Consumer Fraud Multi-State Class would rely upon its deceptive conduct, which they did, suffering damages.

Breaches of Express Warranty,
Implied Warranty of Merchantability/Fitness for a Particular Purpose
and Magnuson Moss Warranty Act, 15 U.S.C. §§ 2301, *et seq.*

103. The Product was manufactured, identified, marketed and sold by Defendant and expressly and impliedly warranted to Plaintiff that it would reliably adhere to her body and provide a continuous dose of maximum strength lidocaine to desensitize nerves and numb pain.

104. Defendant directly marketed the Product to Plaintiff through its advertisements and marketing, through various forms of media, on the packaging, in print circulars, direct mail, product descriptions distributed to resellers, and targeted digital advertising.

105. Defendant knew the product attributes that potential customers like Plaintiff were seeking and developed its marketing and labeling to directly meet those needs and desires.

106. Defendant's representations about the Product were conveyed in writing and promised it would be defect-free, and Plaintiff understood this meant it would reliably adhere to her body and provide a continuous dose of maximum strength lidocaine to desensitize nerves and numb pain.

107. Defendant's representations affirmed and promised that the Product would reliably adhere to her body and provide a continuous dose of maximum strength lidocaine to desensitize nerves.

108. Defendant described the Product so Plaintiff believed that they would reliably adhere to her body and provide a continuous dose of maximum strength lidocaine to desensitize nerves, which became part of the basis of the bargain that it would conform to its affirmations and promises.

109. Defendant had a duty to disclose and/or provide non-deceptive descriptions and marketing of the Product.

110. This duty is based on Defendant's outsized role in the market for this type of Product, a trusted company known for its high-quality Rite Aid brand.

111. Plaintiff recently became aware of Defendant's breach of the Product's warranties.

112. Plaintiff provided or provides notice to Defendant, its agents, representatives, retailers, and their employees that it breached the Product's warranties.

113. Defendant received notice and should have been aware of these issues due to complaints by third-parties, including regulators, competitors, and consumers, to its main offices, and by consumers through online forums.

114. The Product did not conform to its affirmations of fact and promises due to Defendant's actions.

115. The Product was not merchantable because it was not fit to pass in the trade as advertised, not fit for the ordinary purpose for which it was intended and did not conform to the promises or affirmations of fact made on the packaging, container or label, because they were marketed as if they would reliably adhere and provide a continuous dose of maximum strength

lidocaine to desensitize nerves and numb pain.

116. The Product was not merchantable because Defendant had reason to know the particular purpose for which it was bought by Plaintiff, because she expected it would reliably adhere to her body and provide a continuous dose of maximum strength lidocaine to desensitize nerves and numb pain, and she relied on Defendant's skill and judgment to select or furnish such a suitable product.

Fraud

117. Defendant misrepresented and/or omitted the attributes and qualities of the Product, that it would not here for anywhere close to the hours indicated, rendering the "Maximum Strength" claim false, and was unable to desensitize nerves and numb pain.

118. Defendant is one of the largest sellers of OTC products in the world with immense resources and the ability to ensure the products it sold were represented truthfully, yet willingly failed to do so.

119. Defendant knew, or should have known, that the Product was defectively designed based on FDA reports and scientific studies regarding their efficacy.

120. Defendant misrepresented and/or omitted the attributes and qualities of the Product, that it provided maximum strength lidocaine in the percentage indicated, to the areas referenced, and for the time period promised, and would desensitize nerves.

121. Moreover, the records Defendant is required to maintain, and/or the information inconspicuously disclosed to consumers, provided it with actual and constructive knowledge of the falsity and deception, through statements and omissions.

122. Defendant knew of the issues described here yet did not address them.

123. Defendant's fraudulent intent is evinced by its knowledge that the Product was not

consistent with its representations.

Jury Demand and Prayer for Relief

Plaintiff demands a jury trial on all issues.

WHEREFORE, Plaintiff prays for judgment:

1. Declaring this a proper class action, certifying Plaintiff as representative and the undersigned as counsel for the class;
2. Awarding monetary, statutory and/or punitive damages and interest;
3. Awarding costs and expenses, including reasonable fees for Plaintiff's attorneys and experts; and
4. Other and further relief as the Court deems just and proper.

Dated: April 29, 2023

Respectfully submitted,

/s/Spencer Sheehan

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